VYALEV® COMPLETE

Guide to Access and Reimbursement Letter Templates

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use
12 mg/240 mg per mL

INDICATION

VYALEV is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD).

SAFETY CONSIDERATIONS

VYALEV is **contraindicated** in patients who currently take or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension. VYALEV may cause **sudden falling asleep** during daily activities and somnolence; **hallucinations/psychosis**; compulsive behavior or **lack of impulse control**; **infusion site reactions and infections**; **withdrawal-emergent hyperpyrexia** and confusion; **dyskinesia**; **vitamin B6 deficiency and seizures**; **cardiovascular ischemic events**; or worsening **glaucoma**.

The **most common adverse reactions** for VYALEV (VYALEV incidence at least 10% and greater than oral carbidopa/levodopa incidence) were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, and dyskinesia.

This is for informational purposes only and is not intended to provide reimbursement or legal advice.
The information presented here does not guarantee payment or coverage.

Please see additional Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

A LETTER OF MEDICAL NECESSITY CAN HELP SUPPORT THE PRESCRIPTION APPROVAL PROCESS

A letter of medical necessity (LOMN) provides supplemental information to support the use of VYALEV® as an appropriate and necessary treatment for patients with advanced Parkinson's disease.

When to use an LOMN:

- When supplementing a prior authorization submission or accompanying documentation required by payers

Include the following for the LOMN submission:

- Patient's full name, health insurance plan identification number, and date of birth
- Case ID number if a decision has already been rendered
- A brief medical history, including diagnosis, symptoms, allergies, existing comorbidities, and ICD-10-CM/ICD-11 codes
- Clinical support for your recommendation

On the next page is a sample LOMN.

Contact your VYALEV® Complete Field Reimbursement Manager for questions about letters to request coverage.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

SAMPLE LETTER OF MEDICAL NECESSITY

It is the provider's responsibility to ensure that the information included in a letter of medical necessity for VYALEV® is accurate and reflects the patient's medical condition.

[Date]

Attn: [Department]

[Name of health plan]

[Health Plan Mailing address]

Re: [Patient's name] [Patient DOB]

[Policy ID/Group Number]

[Case ID Number if available]

To whom it may concern:

My name is [name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [patient name], to request coverage for [product, dosage, and frequency]. [Patient Name] has been under my care for [X months/years] for the treatment of [disease or symptoms].

I am writing this letter for medical necessity because after working with [Patient name], I believe that [product name] is the best treatment for my patient.

[Provide a brief medical history, including diagnosis, disease manifestations, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)].

[Discuss rationale for using product. Insert your recommendation summary here, including your professional opinion of your patient's impact without treatment].

[List of pertinent medical records] are enclosed, which offer additional support for the medical necessity request for [product name]. Please consider coverage of [product name] for my patient.

Please contact me at [telephone number] to answer any pending questions. I would be pleased to speak to the medical necessity of [product name] for [patient's name]'s [diagnosis]. Thank you in advance for your attention to this request.

Sincerely,

[Physician Name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

Click here to download an LOMN template.

Note: Some payers require use of a specific form to help establish medical necessity.

Contact your VYALEV® Complete Field Reimbursement Manager with questions about specific forms or documentation needed for plans in your local area at 1-866-4VYALEV (1-866-489-2538).

This sample LOMN is presented for informational purposes only and is not intended to provide a product coverage guarantee or legal advice.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

A LETTER OF MEDICAL EXCEPTION CAN BE USED WHEN A PAYER'S POLICY DOESN'T COVER VYALEV®

If VYALEV® is not covered by an insurance plan, a letter of medical exception (LOME) can be used to request that a payer consider covering it.

When to use an LOME:

- When treatments become available and payers have not determined coverage or no policy is established
- The letter provides supplemental information to support the use of VYALEV® as a medically necessary treatment for the patient

Include the following for the LOME submission:

- Pertinent patient medical records
- VYALEV® FDA approval letter
- VYALEV® prescribing information
- Any other supporting documentation

On the next page is a sample LOME.

Contact your VYALEV® Complete Field Reimbursement Manager for questions about letters to request coverage.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

SAMPLE LETTER OF MEDICAL EXCEPTION

It is the provider's responsibility to ensure that the information included in a letter of medical exception for VYALEV® is accurate and reflects the patient's medical condition.

[Date]

Attn: [Department]

[Name of health plan]

[Health Plan Mailing address]

Re: [Patient's name] [Patient DOB]

[Policy ID/Group Number]

[Case ID Number if available]

To whom it may concern:

My name is [name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [patient name], to request an authorization for treatment with [product, dosage, and frequency]. [Patient Name] has been under my care for [X months/years] for the treatment of [disease or symptoms].

[Provide a brief medical history, including diagnosis, disease manifestations, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)].

[Discuss rationale for using product. Insert your recommendation summary here, including your professional opinion of your patient's impact without treatment].

The following are enclosed, which offer additional support for this medical exception request for [product name]:

- [List of pertinent medical records]
- [FDA approval letter for product]
- [Prescribing Information for product]
- [Other supporting documentation]

Please contact me at [telephone number] for any additional information you may require to support coverage of [product name] for [patient's name]. Thank you in advance for your attention to this request.

Sincerely,

[Physician Name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

Click here to download an LOME template.

Note: Some payers require use of a specific form to help establish medical exception.

Contact your VYALEV® Complete Field Reimbursement Manager with questions about specific forms or documentation needed for plans in your local area at 1-866-4VYALEV (1-866-489-2538).

This sample LOME is presented for informational purposes only and is not intended to provide a product coverage guarantee or legal advice.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

APPEAL LETTERS HELP SUPPORT ACCESS TO VYALEV® IN THE EVENT OF A COVERAGE DENIAL

When a health insurance plan denies coverage of a prescribed treatment or service, patients and prescribers have the right to request an appeal. The first step when filing an appeal is to understand the reason for the denial, which is included in the denial letter or Explanation of Benefits (EOB).

When to use an appeal letter:

- When a payer denies coverage of VYALEV®, or to appeal a requirement to try other therapies prior to initiating VYALEV®

What to include in the appeal letter submission:

Consider including an explanation of why you believe VYALEV® is the most appropriate treatment option for the patient, based on medical history and diagnosis, such as:

- Brief medical history, including disease manifestations and ICD-10 code(s)
- Clinical rationale for using VYALEV®, including clinical opinion of the impact on the patient without treatment

After submitting the letter and supporting documentation via the payer's preferred method, the payer must review and decide on coverage within:

For urgent care

For non-urgent care

For services already provided

On the next page is a sample appeal letter.

Contact your VYALEV® Complete Field Reimbursement Manager for questions about letters of appeal.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

SAMPLE APPEAL LETTER

It is the provider's responsibility to ensure that the information included in an appeal letter for VYALEV® is accurate and reflects the patient's medical condition.

[Date]

Re: [Patient's name] [Patient DOB]

Attn: [Department]

[Policy ID/Group Number]

[Name of health plan]

[Case ID Number if available]

[Health Plan Mailing address]

[Date of Service]

To whom it may concern:

My name is [HCPs name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [Patient Name], to request coverage for [product name] [generic]. [Patient Name] has been under my care for [X months/years] for the treatment of [disease or symptoms].

We understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, we believe that [product, dosage, frequency] is the appropriate treatment for my patient. In support of our recommendation for [product] treatment, we have provided an overview of my patient's relevant clinical history below.

[Provide a brief medical history, including diagnosis, disease manifestations, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)].

[Discuss rationale for using product. Insert your recommendation summary here, including your professional opinion of your patient's impact without treatment].

[List of pertinent medical records] are enclosed, which offer additional support for this request to reconsider coverage of [product name] for my patient.

Please feel free to contact me, [name], at [telephone number] or [patient's name] at [phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

Click here to download an appeal letter template.

Contact your VYALEV® Complete Field Reimbursement Manager with questions about the appeal process at 1-866-4VYALEV (1-866-489-2538).

This sample appeal letter is presented for informational purposes only and is not intended to provide a product coverage guarantee or legal advice.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

INDICATION AND IMPORTANT SAFETY INFORMATION

FOR VYALEV® (foscarbidopa/foslevodopa)

INDICATION

VYALEV is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD).

IMPORTANT SAFETY INFORMATION

Contraindications

VYALEV® (foscarbidopa/foslevodopa) is contraindicated in patients who are currently taking or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension.

Warnings and Precautions

Falling Asleep During Activities of Daily Living and Somnolence: Patients treated with levodopa (the active metabolite of VYALEV) have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes resulted in accidents. Although many of these patients reported somnolence while on levodopa, some perceived that they had no warning signs, such as excessive drowsiness, and believed they were alert immediately prior to the event (sleep attack). Some of these events have been reported more than one year after initiation of treatment. For this reason, prescribers should continually assess VYALEV-treated patients for drowsiness or sleepiness. Advise patients about the potential to develop drowsiness with VYALEV and ask about factors that may increase risk of somnolence. Consider discontinuing VYALEV in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation. If VYALEV is continued, patients should be advised not to drive and to avoid other potentially dangerous activities that might result in harm if the patient becomes somnolent. There is insufficient information to establish that dose reduction will eliminate episodes of falling asleep while engaged in activities of daily living.

Hallucinations/Psychosis: There is an increased risk for hallucinations and psychosis in patients taking VYALEV. Hallucinations associated with levodopa may present shortly after the initiation of therapy and may be responsive to dose reduction of VYALEV or other concomitantly administered medications. Patients with a major psychotic disorder should not be treated with VYALEV.

Impulse Control/Compulsive Behaviors: Patients may experience intense urges while on VYALEV. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while on VYALEV. Consider reducing the dose or discontinuing VYALEV if a patient develops such urges.

Infusion Site Reactions and Infections: VYALEV can cause infusion site reactions and infections. Various types of reactions at the infusion site have been reported, including erythema, pain, edema, nodules, warmth, swelling, and others. The most frequent infusion site infection reported was cellulitis. If an infection is suspected at the infusion site, the cannula should be removed. In such a case, either a new cannula should be placed at a new infusion site or, in the event of a prolonged interruption, prescribe an oral carbidopa/levodopa product until the patient is able to resume VYALEV.

Withdrawal-emergent hyperpyrexia and confusion, a symptom complex that resembles neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal, or change in dopaminergic therapy. Avoid sudden discontinuation or rapid dose reduction of VYALEV.

Please see additional Important Safety Information for VYALEV® on page 9.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

IMPORTANT SAFETY INFORMATION (continued)

FOR VYALEV® (foscarbidopa/foslevodopa)

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Dyskinesia: VYALEV may cause or exacerbate dyskinesias, which may require a dose reduction of VYALEV or other medicines used to treat Parkinson's disease.

Vitamin B6 Deficiency and Seizures: Treatment with carbidopa/levodopa (the active metabolites of VYALEV) may contribute to reduced vitamin B6 levels and higher doses of carbidopa/levodopa may increase the risk. Seizures associated with vitamin B6 deficiency have been reported in patients taking carbidopa/levodopa. Evaluate vitamin B6 levels prior to initiation of VYALEV and during treatment or if symptoms of vitamin B6 deficiency are identified and supplement with vitamin B6 as necessary.

Cardiovascular Ischemic Events: Myocardial infarction and arrhythmia were reported in patients taking carbidopa/levodopa (the active metabolites of VYALEV). Ask patients about symptoms of ischemic heart disease and arrhythmia, especially those with a history of myocardial infarction or cardiac arrhythmias.

Glaucoma: Monitor patients with glaucoma after starting VYALEV as it may cause increased intraocular pressure.

Adverse Reactions

The most common adverse reactions for VYALEV that occurred in ≥3% of patients, and at least 2% difference from oral immediate-release carbidopa/levodopa, were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, dyskinesia, On and Off phenomenon, balance disorder, constipation, peripheral swelling, agitation, insomnia, psychotic disorder, and dyspnea.

Drug Interactions

- The use of nonselective MAO inhibitors is contraindicated. Use of selective MAO-B inhibitors may be associated with orthostatic hypotension.
- Concurrent administration with antihypertensives can cause symptomatic postural hypotension, which may require a dose adjustment of the antihypertensive.
- Coadministration with dopamine D2 antagonists or isoniazid may reduce the effectiveness of VYALEV.

Dosage Forms and Strengths

VYALEV (foscarbidopa and foslevodopa) injection for subcutaneous use is available in a 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL (12 mg foscarbidopa and 240 mg foslevodopa per mL) solution.

Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use

SUPPORT AND HELP WHEN NEEDED WITH VYALEV® COMPLETE

HELPING SUPPORT TIMELY ACCESS TO VYALEV® TREATMENT

VYALEV® Complete Field Reimbursement Managers have expertise in insurance policies and processes. They will partner with you to help navigate insurance coverage and authorizations.

Your VYALEV® Complete Field Reimbursement Manager provides:

- Medical policy education for Medicare, Medicare Advantage, and local and national commercial plans
- Help with individual patients' unique insurance situations and authorization requirements
- Education in the coding and billing process
- Specialty Pharmacy fulfillment updates

HELPING PATIENTS WITH PERSONALIZED SUPPORT

Once patients are prescribed VYALEV® and enrolled in VYALEV® Complete, they will be assigned a dedicated Nurse Ambassador* as a single point of contact. This Ambassador will get to know the best ways to support your patient and their care partner throughout their VYALEV® treatment journey.

Contact your VYALEV® Complete Field Reimbursement Manager for questions about reimbursement at 1-866-4VYALEV (1-866-489-2538).

*Nurse Ambassadors are provided by AbbVie and do not provide medical advice or work under the direction of the prescribing health care professional (HCP). They are trained to direct patients to speak with their HCP about any treatment-related questions, including further referrals.

Please see Indication and Important Safety Information for VYALEV® on pages 8 and 9.
Please see accompanying full VYALEV® Prescribing Information or visit www.rxabbvie.com/pdf/vyalev_pi.pdf

abbvie

US-VYAL-260145 April 2026 034786

VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use